

## **REMARKS**

Applicants acknowledge receipt of an Office Action dated October 6, 2005. In this response applicants have revised claims 32 – 39 while canceling claims 29 and 30, without prejudice or disclaimer. New claims 42-47 are amply supported by the specification and more clearly states what applicants regard as their invention. The other claim changes are largely of an editorial nature.

Since no new matter is involved in either the addition of claims 42-47 or the revision of the other claims, applicants request entry of the amendment. Upon entry, claims 31-47 will be pending.

Reconsideration of the present application is respectfully requested in view of the foregoing amendments and these remarks.

### **Double Patenting Rejection**

On page 2 of the Office Action, the PTO has rejected claim 29 over claims 1-27 of U.S. Patent 6,610,530. Without acquiescing to the stated grounds for this rejection, applicants have decided to advance prosecution by filing the accompanying terminal disclaimer, thereby obviating the rejection and warranting its withdrawal.

### **Rejections Under 35 U.S.C. § 101**

On page 3 of the Office Action, the examiner alleges that claims 30-37 are “directed to non-statutory subject matter” because “a *temporary* change in the metabolism of the microorganism, as prescribed by the claims in question, does not alter it from the counterpart in nature” (emphasis added).

By his use of the “temporary” qualifier, the examiner is heard to acknowledge that the “lactic acid bacterial cell” of original claim 30 is altered metabolically, at least for so long as the presently recited “conditions” pertain. Further, the examiner appears not to question that the alternation(s) in question are observable or demonstrable, such that the skilled person, informed by the present specification, could distinguish a cell so altered from one that is not. Finally, there is no contention of record (and none is reasonably available) that the aforementioned conditions are other than wholly artificial; hence, the presence and impact of these conditions undoubtedly are indicative of the hand of man.

Accordingly, the stated rationale for the subject rejection resolves to the alleged “temporary” quality of the “change.” Yet there is no basis (and the examiner cites none) for contending that the artificial (non-natural) status of a claimed composition is ineffective, with respect to distinguishing that composition from a natural counterpart, simply because the status is transient. To the contrary, the PTO’s review court has held that a claimed composition cannot be excluded from Section 101 of the Patent Statute, as the examiner would do here, simply because the composition, as claimed, is transitory, unstable, or non-isolatable. *In re Breslow*, 616 F.2d 516, 521 (CCPA 1980) (“...the PTO would read into § 101 a requirement that compositions of matter must be stable .... We see no good reason to do so.”), *cited with approval at* Section 2164.01(b), MANUAL OF PATENT EXAMINATION PROCEDURE.

Accordingly, there is no rationale for this rejection that is cognizable as a matter of law. Nevertheless, in an effort to facilitate prosecution applicants have revised the rejected claims to prescribe a “culture” of lactic acid bacterial cells that are characterized by both a reduced glycolytic flux and a respiratory metabolism under aerobic conditions. As the skilled person would readily appreciate from the present specification, a culture of such cells is novel to the world, including the natural world (see discussion in next section).

For these reasons, applications request that the examiner reconsider and withdraw the rejection under Section 101.

### **Rejections Under 35 U.S.C. § 102**

On page 4 of the Office Action, the examiner has rejected claims 30-41 as anticipated by each of U.S. patents No. 6,284,518 to Henick-Kling *et al.*, No. 5,798,237 to Picataggio *et al.*, No. 4,115,199 to Porubcan *et al.*, No. 3,655,396 to Goto *et al.*, and No. 5,075,226 to Kaneko *et al.* As demonstrated below, none of the cited patents places in the hands of the interested public a culture of lactic acid bacterial cells characterized not only by a reduced glycolytic flux but also by a respiratory metabolism in an aerobic environment:

- (1) Henick-Kling describes the production of lactic acid bacteria, in particular *Leuconostoc oenos* or a *Lactobacillus spp.*, using a fructose/glucose mixture in which fructose is the primary carbon source. Even if the disclosed mixture were deemed to provide a readily available carbon source, resulting in a reduced glycolytic flux for cultured cells, the reference says nothing at all that implicates a respiratory metabolism.

- (2) Picataggio relates to a lactic acid bacterial cell that has been modified genetically to possess the ability to ferment lignocellulosic, xylose-containing biomass, producing lactic acid. Again, nothing in this reference even hints at a respiratory metabolism for cultured cells.
- (3) Porubcan teaches a concentrated bacterial culture, which, in the presence of a suitable phosphate salt, is suitable for direct vat inoculation. Porubcan makes no mention of a respiratory metabolism.
- (4) Goto describes preparing an animal feed by means of a microorganism that, under aerobic conditions, can metabolize lactic acid. In sharp contrast, the presently claimed invention relates to a culture of lactic acid bacterial cells, which, by definition, produce rather than metabolize lactic acid. Thus, nothing in Goto could have suggested, let alone taught, the combination of a reduced glycolytic flux and a respiratory metabolism, as presently recited.
- (5) Kaneko describes the production of diacetyl and acetoin via bacterial fermentation, under aeration, in the presence of a porphyrin compound. Kaneko's methodology does not involve introducing a reduced glycolytic flux, because his medium contains a sugar source that lactic acid bacteria can readily utilize (see column 2, lines 63-64), and the only carbon source mentioned, glucose, likewise is readily utilized by the lactic acid bacterial cell. Additionally, there is no teaching in Kaneko of limiting the concentration of a readily fermentable sugar; rather, the reference counsels supplying such a sugar at 20 g/l (column 4, line 34). Thus, the lactic acid bacterial cells in Kaneko's method are not starved with respect to carbon source (compare present specification, e.g., at paragraphs 0069 and 0070).

At least for these reasons, applicants submit that none of the cited patents undercuts the novelty of the present claims, since none teaches every recited aspect of the claimed invention. Furthermore, no permutation of teachings from the art of record could have prompted the skilled artisan to effect, for lactic acid bacterial cells in a culture, not only a reduced glycolytic flux but also, in an aerobic environment, a respiratory-metabolism capability. Certainly, the art in no way suggests the surprising improvement in biomass yield that this combination achieves, pursuant to the claimed invention. Accordingly, applicants request that the examiner reconsider and withdraw each of the pending prior-art rejections.

### CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that all of the pending claims are now in condition for allowance. An early notice to this effect is earnestly solicited. If there are any questions regarding the application, the Examiner is invited to contact the undersigned at the number below.

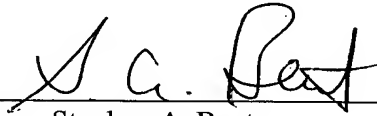
Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 4 April 2006  
FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5404  
Facsimile: (202) 672-5399

By   
Stephen A. Bent  
Attorney for Applicants  
Registration No. 29,768